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Research Paper

Smallpox Vaccination

Comparison of Self-Reported and Electronic Vaccine Records in the Millennium Cohort Study

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KEY WORDS

smallpox vaccine, questionnaires, military medicine, quality of life, validation studies

ABBREVIATIONS

| | |
|----------|--|
| CI | confidence interval |
| DMDC | Defense Manpower Data Center |
| DoD | US Department of Defense |
| GWOT | Global War on Terrorism |
| κ | kappa statistic |
| SF-36V | Medical Outcomes Study Short Form 36-item Health Survey for Veterans |

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ABSTRACT

In December 2002, the US Government implemented policy to immunize health workers, first responders and military personnel against smallpox in preparation for a possible bioterrorist attack. Self-reported vaccination data are commonly used in epidemiologic research and may be used to determine vaccination status in a public health emergency. To establish a measure of reliability, the agreement between self-reported smallpox vaccination and electronic vaccination records was examined using data from the Millennium Cohort Study. Descriptive measures and a kappa statistic were calculated for data from 54,066 Millennium Cohort Study participants. Multivariable modeling adjusting for potential confounders was used to investigate vaccination agreement status and health metrics, as measured by the Short Form 36-Item Health Survey for Veterans (SF-36V) and hospitalization data. Substantial agreement ($\kappa = 0.62$) was found between self-report and electronic recording of smallpox vaccination. Of all participants with an electronic record of smallpox vaccination, 90% self-reported being vaccinated; and of all participants with no electronic record of vaccination, 82% self-reported not receiving a vaccination. There was no significant difference in hospitalization experience prior to questionnaire completion between vaccinated and unvaccinated participants. While overall scores on the SF-36V suggested a healthy population, participants whose self-reported vaccination status did not match electronic records had slightly lower adjusted mean scores for some scales. These results indicate strong reliability in self-reported smallpox vaccination and also suggest that discordant reporting of smallpox vaccination is not associated with substantial differences in health among Millennium Cohort participants.

INTRODUCTION

The World Health Organization announced in 1980 that naturally occurring smallpox had been eradicated worldwide following the last case reported in Somalia in 1977.^{1,2} Once the risk of natural infection had disappeared, routine vaccination was discontinued. Laboratories with existing smallpox (variola virus) were requested to destroy the virus or turn their stocks over to one of two collaborating centers.^{2,3} It has been suggested, however, that the variola virus may have been retained for use as a biological weapon.⁴ In the wake of the September 11, 2001 terrorist attacks, the US Government began to immunize health workers, first responders and military personnel against smallpox in preparation for a possible bioterrorist attack.³ From December 2002–January 2005, nearly 40,000 health care workers and first responders were inoculated against smallpox as well as more than 730,000 US military personnel.⁵

When possible, establishing a measure of reliability in self-reported data will yield insight into potential strengths and limitations of questionnaire data. Most adult vaccine studies have indicated that self-report is a moderately reliable method to determine an individual's vaccination status,⁶⁻¹³ but no previous study to date has investigated the accuracy of self-reported smallpox vaccination. Previous studies have found that self-report of adult influenza and pneumococcal vaccination is highly sensitive (70–100%) but less specific (22–89%).^{6,7,10,13} Using limited anthrax vaccine data, the sensitivity of self-reported anthrax vaccination among 1991 Gulf War veterans was 73.9%.⁸ Among Millennium Cohort Study members, greater than substantial agreement ($\kappa = 0.80$) was found between self-report and electronic anthrax vaccination status.¹¹ Two previous studies found smallpox vaccinees were accurately able to self-report their reaction to the smallpox vaccination.^{14,15} Using data from the Millennium Cohort Study, the purpose of this study was to investigate agreement between self-reported smallpox vaccination

and electronic vaccination records in a large, population-based military cohort. Further, this study examines the variation in vaccination data concordance as it pertains to subjective and objective measures of physical and mental health.

METHODS

Study population and data sources. The Millennium Cohort Study was launched in 2001 to gather and evaluate population-based data on behavioral and occupational risk factors related to military service that may be associated with adverse health outcomes.^{16,17} A randomly selected group from all US military personnel serving in 2000 was invited to participate in the first panel. Those who had been deployed to Southwest Asia, Bosnia or Kosovo (January 1, 1998–September 1, 2000), members of the Reserve or National Guard and women were oversampled to ensure sufficient power to detect differences in these smaller population subgroups. Of the 77,047 enrolled in this first panel, 55,021 (71.4%) completed the follow-up questionnaire between June 2004 and February 2006. The population for the current study included Millennium Cohort Study participants with complete demographic and military-specific data who consented at baseline, participated in the follow-up, and answered the smallpox vaccine question on the follow-up questionnaire.

The Defense Manpower Data Center (DMDC) provided demographic and military-specific data from electronic personnel files, including gender, birth date, highest education level, marital status, race/ethnicity, deployment experience (no deployment experience; Gulf War, Bosnia, Kosovo or Southwest Asia deployment experience before the Global War on Terrorism (GWOT); or deployment experience in support of GWOT between 2001 and 2006), pay grade, service component (active duty or Reserve/National Guard), service branch (Army, Air Force, Navy, Coast Guard or Marine Corps) and primary military occupations.

Smallpox vaccination data. The following question was included on the 2004–2006 questionnaire to measure smallpox vaccination, “In the past three years have you received the smallpox vaccine?” The questionnaire did not include information about the vaccine’s administration or skin reaction at the injection site. Electronic smallpox vaccination data were obtained from the Defense Enrollment and Eligibility Reporting System at DMDC which maintains an electronic database of all vaccinations given to military service members. A participant was classified as vaccinated in the electronic records if a smallpox vaccination was documented in the three years prior to completing the follow-up questionnaire.

Health metrics. The baseline and follow-up questionnaires of the Millennium Cohort Study include questions to assess physical health, mental health, and other health outcomes. Differences between vaccination concordance groups were examined as they pertained to prior hospitalization and subjective health metrics. Inpatient data were used to investigate differences in objective measures of health using hospitalization as the outcome of interest among active-duty service members. Participants were classified as hospitalized if, in the 12 months prior to completing the survey, they were hospitalized for any cause, excluding the following International Classification of Diseases, Ninth Revision, Clinical Modification diagnosis codes: complications of pregnancy, childbirth, and the puerperium (630–77), congenital anomalies (740–59), and certain conditions originating in the perinatal period (760–79). Hospitalization data were obtained from the

computerized databases of standardized discharge diagnoses for hospitalizations within the Military Health System and for hospitalizations billed to the Department of Defense by nonmilitary facilities. These databases contain hospitalization summaries including dates of admission and discharge, and up to eight individual discharge diagnoses for each encounter, which are uniformly coded across US military services. The Medical Outcomes Study Short Form 36-Item Health Survey for Veterans (SF-36V), a modified version of the MOS Short Form 36 (SF-36) that is contained within the Millennium Cohort questionnaire, was used to compare differences in physical and mental health.^{18–22} Like the SF-36, the SF-36V uses standardized scoring algorithms to assess eight health scales: physical functioning, role limitations caused by physical problems, bodily pain, general health, vitality, social functioning, role limitations caused by emotional problems and mental health. Higher scores are associated with better health status. Unique identifiers were used to link the immunization, demographic and hospitalization data to the Millennium Cohort participants.

Statistical analysis. A descriptive investigation was completed to compare self-reported vaccination status and electronic vaccination records. The percentage of disagreement between self-reported vaccination and electronic documentation of smallpox vaccination was reported. To measure the degree of nonrandom agreement between self-reported smallpox vaccination and electronic smallpox vaccine records the kappa statistic was used.²³ A κ between 0.8–1.0 was defined as “greater than substantial agreement,” between 0.6–0.8 as “substantial agreement,” between 0.4–0.6 as “moderate agreement,” between 0.2–0.4 as “fair agreement,” and between 0.0–0.2 as “slight or poor agreement.”²⁴

To assess associations between prior hospitalization and vaccination concordance status multivariable logistic regression was used, adjusting for all demographic and military-related variables. Analysis of variance was performed to investigate the association between self-reported health status (SF-36V) and vaccination concordance, adjusting for all demographic and military-related variables. Vaccination concordance was divided into four categories: (1) participants who reported not receiving a smallpox vaccination with concurrence from the electronic records, (2) participants who reported receiving a smallpox vaccination but electronic records did not reflect vaccination, (3) participants who reported not receiving a smallpox vaccination but electronic records reflected vaccination and (4) participants who reported receiving a smallpox vaccination with concurrence from the electronic records.

Regression diagnostics, including examining covariates for multicollinearity and goodness of fit test, were performed. All data analyses were completed using SAS Version 9.1.3 (SAS Institute, Inc., Cary, North Carolina).

RESULTS

This study included 54,066 Millennium Cohort participants who completed the follow-up questionnaire between June 2004–February 2006, answered the smallpox vaccination question, and had complete demographic and military-specific data. The majority of participants self-reported they had not received a smallpox vaccination in the three years prior to completing the questionnaire ($n = 34,859$, 64.5%). The electronic vaccination records confirmed 33,614 (96.4%) of these participants had not received a smallpox vaccination. A smaller percentage of participants

Table 1 **Characteristics of Millennium Cohort Study participants by smallpox vaccination status**

| Characteristic | Study sample N = 54,066 %* | Concordant† unvaccinated N = 33,614 n (%) | Smallpox vaccination status | | Concordant† vaccinated N = 11,670 n (%) | p-value‡ |
|-----------------------------------|----------------------------------|--|--|---|--|----------|
| | | | Discordant† self-report vaccinated n = 7,537 n (%) | Discordant† electronic vaccinated N = 1,245 n (%) | | |
| Gender | | | | | | <.0001 |
| Male | 73.4 | 23,477 (69.8) | 5,935 (78.7) | 922 (74.1) | 9,331 (80.0) | |
| Female | 26.6 | 10,137 (30.2) | 1,602 (21.3) | 323 (25.9) | 2,339 (20.0) | |
| Birth Year | | | | | | <.0001 |
| Before 1960 | 24.5 | 9,072 (27.0) | 2,123 (28.2) | 204 (16.4) | 1,849 (15.8) | |
| 1960–1969 | 40.6 | 13,497 (40.2) | 3,144 (41.7) | 559 (44.9) | 4,723 (40.5) | |
| 1970–1979 | 30.8 | 9,896 (29.4) | 1,923 (25.5) | 429 (34.5) | 4,408 (37.8) | |
| 1980 or later | 4.1 | 1,149 (3.4) | 347 (4.6) | 53 (4.3) | 690 (5.9) | |
| Education | | | | | | <.0001 |
| High school or less | 45.6 | 13,569 (40.4) | 3,780 (50.2) | 675 (54.2) | 6,621 (56.7) | |
| Some college | 17.8 | 6,942 (20.7) | 1,104 (14.7) | 207 (16.6) | 1,367 (11.7) | |
| Bachelor's degree | 22.1 | 7,603 (22.6) | 1,678 (22.3) | 227 (18.2) | 2,428 (20.8) | |
| Advanced degree | 14.6 | 5,500 (16.4) | 975 (12.9) | 136 (10.9) | 1,254 (10.8) | |
| Marital status | | | | | | 0.009 |
| Not married | 26.7 | 8,871 (26.4) | 2,038 (27.0) | 301 (24.2) | 3,228 (27.7) | |
| Married | 73.3 | 24,743 (73.6) | 5,499 (73.0) | 944 (75.8) | 8,442 (72.3) | |
| Race/ethnicity | | | | | | <.0001 |
| White non-Hispanic | 71.0 | 24,209 (72.0) | 5,178 (68.7) | 829 (66.6) | 8,185 (70.1) | |
| Black non-Hispanic | 12.1 | 4,031 (12.0) | 1,032 (13.7) | 212 (17.0) | 1,279 (11.0) | |
| Other | 16.9 | 5,374 (16.0) | 1,327 (17.6) | 204 (16.4) | 2,206 (18.9) | |
| Deployment experience§ | | | | | | <.0001 |
| No deployment | 46.3 | 19,762 (58.8) | 3,635 (48.2) | 257 (20.6) | 1,398 (12.0) | |
| Pre-GWOT deployment | 23.1 | 9,875 (29.4) | 1,800 (23.9) | 142 (11.4) | 673 (5.8) | |
| 2001–2006 GWOT deployment | 15.3 | 1,835 (5.5) | 1,135 (15.1) | 397 (31.9) | 4,923 (42.2) | |
| Both pre-GWOT and GWOT deployment | 15.2 | 2,142 (6.4) | 967 (12.8) | 449 (36.1) | 4,676 (40.1) | |
| Military rank | | | | | | <.0001 |
| Enlisted | 70.8 | 23,528 (70.0) | 5,434 (72.1) | 946 (76.0) | 8,374 (71.8) | |
| Officer | 29.2 | 10,086 (30.0) | 2,103 (27.9) | 299 (24.0) | 3,296 (28.2) | |
| Service component | | | | | | <.0001 |
| Reserve/Guard | 53.4 | 18,560 (55.2) | 4,266 (56.6) | 476 (38.2) | 5,570 (47.7) | |
| Active duty | 46.6 | 15,054 (44.8) | 3,271 (43.4) | 769 (61.8) | 6,100 (52.3) | |
| Branch of service | | | | | | <.0001 |
| Army | 47.7 | 15,035 (44.7) | 3,624 (48.1) | 554 (44.5) | 6,577 (56.4) | |
| Air Force | 30.3 | 10,540 (31.4) | 1,673 (22.2) | 511 (41.0) | 3,644 (31.2) | |
| Navy/Coast Guard | 18.0 | 6,752 (20.1) | 1,823 (24.2) | 151 (12.1) | 1,017 (8.7) | |
| Marine Corps | 4.0 | 1,287 (3.8) | 417 (5.5) | 29 (2.3) | 432 (3.7) | |
| Occupational category | | | | | | <.0001 |
| Combat specialists | 19.2 | 5,977 (17.8) | 1,514 (20.1) | 235 (18.9) | 2,663 (22.8) | |
| Health care specialists | 11.4 | 4,106 (12.2) | 526 (7.0) | 171 (13.7) | 1,352 (12.0) | |
| Functional support | 22.9 | 8,449 (25.1) | 1,820 (24.2) | 236 (19.0) | 1,879 (16.1) | |
| Others | 46.5 | 15,082 (44.9) | 3,677 (48.8) | 603 (48.4) | 5,776 (49.5) | |

*Percentages rounded and may not sum to 100. †Concordant unvaccinated, both self-report and electronic database reflect no vaccination; Discordant self-report vaccinated, self-reported vaccination but electronic database reflects no vaccination; Discordant electronic vaccinated, self-reported no vaccination but electronic database reflects vaccination; Concordant vaccinated, both self-report and electronic database reflect vaccination. ‡Pearson chi-square p value examining unadjusted associations between smallpox vaccination status and individual characteristics. §Pre-GWOT deployment, deployed to the 1991 Gulf War or to Bosnia, Kosovo or Southwest Asia between January 1, 1998, and September 30, 2000; 2001–2006 GWOT deployment, deployed in support of the Global War on Terrorism before completion of follow-up survey.

reported receiving a smallpox vaccination (n = 19,207, 35.5%). Of these participants, 11,670 (60.8%) had an electronic record indicating vaccination. Among all participants, 8,782 (16.2%) had discordant results. Most participants with discordant results reported receiving a vaccination even though electronic records indicated

no vaccination (n = 7,537; 13.9%). There were 1,245 (2.3%) with electronic documentation of smallpox vaccination who reported not receiving the vaccination.

The demographic characteristics of these four vaccination groups are compared in Table 1. A greater proportion of those

Table 2 Agreement* between self-reported smallpox vaccination and electronic records

| | Electronic record | |
|--|-------------------------|----------------------------|
| | Vaccine (N = 12,915) | No vaccine (N = 41,151) |
| Self-report Vaccine (N = 19,207) | 11,670 | 7,537 |
| No vaccine (N = 34,859) | 1,245 | 33,614 |

*Agreement measures for self-report are as follows: $\kappa = 0.62$; 90.4% of participants with electronic documentation of smallpox vaccination self-reported being vaccinated; 81.7% of participants with no electronic record of vaccination self-reported not receiving a vaccination.

who had an electronically confirmed self-reported vaccination (concordant vaccinated) were male, younger, less educated, deployed in support of GWOT, active duty, Army service members and combat specialists than those who reported not receiving a vaccination, which was confirmed by the electronic vaccination record (concordant unvaccinated). A larger percentage of participants who self-reported vaccination with no confirmation by electronic record (discordant self-reported vaccinated) were older, not deployed in support of GWOT, Reserve/National Guard, in the Navy/Coast Guard or Marine Corps and working in functional support roles than were concordant vaccinated participants.

Of all participants with electronic documentation of smallpox vaccination, 90% self-reported being vaccinated; and of all participants with no electronic record of vaccination, 82% self-reported not receiving a vaccination (Table 2). The overall κ statistic indicated substantial agreement ($\kappa = 0.62$). While most of the κ statistics calculated for the categories of demographic characteristics indicated substantial agreement ($\kappa = 0.6$ – 0.8), participants who were born before 1960 ($\kappa = 0.51$), those without GWOT deployment experience ($\kappa = 0.35$), Navy/Coast Guard service members ($\kappa = 0.41$) and Marines ($\kappa = 0.53$) had lower agreement scores.

After adjustment for gender, age, education, marital status, race/ethnicity, deployment experience, pay grade, service branch and occupation, hospitalization rates for any cause in the year prior to survey completion were not significantly different between the vaccination groups among active-duty service members (Table 3).

The SF-36V mean scores for the eight scales were adjusted for gender, age, education, marital status, race/ethnicity, deployment experience, pay grade, service component, service branch and occupation (Table 3). Overall, the SF-36V adjusted mean scores were relatively high for each vaccination group, indicating good health. However, significantly lower adjusted mean scores for social functioning and role limitations caused by physical and emotional problems were found among participants whose electronic records reflected no vaccination but who self-reported receiving the smallpox vaccination when compared to groups with concordant status. The adjusted mean score for vitality was slightly but significantly lower among participants who reported they did not receive a vaccination but whose electronic records reflected a vaccination. Additionally, the adjusted mean score for physical functioning and general health were slightly but significantly higher among the concordant vaccinated group compared to the concordant unvaccinated group.

DISCUSSION

This study demonstrated that self-reported smallpox vaccination records are consistent with electronic military vaccination records, with 84% of participants having identical responses from the two sources. Agreement levels,²⁴ as demonstrated by the kappa statistic, suggest substantial agreement between electronic and self-reported smallpox vaccination ($\kappa = 0.62$). While, to our knowledge, no previous studies have investigated the validity of self-reported smallpox vaccination, previous studies have examined other vaccinations given to adults. A slightly higher agreement ($\kappa = 0.69$) was found between self report and medical records for pneumococcal vaccination among Australian adults.⁶ Two other

Table 3 Adjusted odds of prior hospitalization and adjusted means of SF-36V health scores among Millennium Cohort participants* by smallpox vaccination status

| Health outcome | Smallpox vaccination status | | | |
|-----------------------------------|---|---|--|--|
| | Concordant† unvaccinated OR (95% CI)‡ | Discordant† self-report vaccinated OR (95% CI) | Discordant† electronic vaccinated OR (95% CI) | Concordant† vaccinated OR (95% CI) |
| Any-cause hospitalization§ | 1.00 | 1.19 (0.97–1.47) | 0.88 (0.57–1.35) | 0.88 (0.71–1.10) |
| SF-36V¶ | Mean | Mean | Mean | Mean |
| Physical functioning | 92.7 ¹ | 92.4 ¹ | 92.0 ¹ | 93.5 ² |
| Role physical | 93.6 ¹ | 92.8 ² | 93.7 ^{1,2} | 94.2 ¹ |
| Bodily pain | 76.3 ^{1,2} | 75.6 ² | 74.9 ^{1,2} | 76.6 ¹ |
| General health | 76.9 ¹ | 76.6 ¹ | 75.4 ¹ | 78.2 ² |
| Social functioning | 88.0 ¹ | 86.5 ² | 87.5 ^{1,2} | 88.3 ¹ |
| Role emotional | 94.0 ¹ | 93.2 ² | 93.9 ^{1,2} | 94.2 ¹ |
| Mental health | 78.6 ¹ | 77.7 ² | 77.7 ^{1,2} | 78.4 ^{1,2} |
| Vitality | 58.8 ^{1,2} | 58.4 ² | 56.6 ³ | 59.4 ¹ |

*Participants whose SF-36V component could not be scored due to insufficient questionnaire responses were removed from analyses (n varies by component; maximum removed: 446). †Concordant unvaccinated, both self-report and electronic database reflect no vaccination (reference group); Discordant self-report vaccinated, self-reported vaccination but electronic database reflects no vaccination; Discordant electronic vaccinated, self-reported no vaccination but electronic database reflects vaccination; Concordant vaccinated, both self-report and electronic database reflect vaccination. ‡Odds ratio (OR), 95% confidence interval (CI), and mean are adjusted for gender, age, education, marital status, race/ethnicity, deployment experience, pay grade, service component (SF-36V only), service branch, and occupation. §Hospitalization analysis includes active-duty service members only and reflects odds of any-cause admission in the year prior to survey response. ¶SF-36V, Medical Outcomes Study Short Form 36-Item Health Survey for Veterans. ¹⁻³ Different numbers indicate vaccination status scores that are significantly different from each other ($p < 0.05$) using Scheffe's adjustment for multiple comparisons.

studies, however, conducted among elderly Department of Veterans Affairs patients have found lower agreement ($\kappa = 0.18$ and 0.42) between self-report and medical record documentation for pneumococcal vaccination.^{7,10} Among Millennium Cohort participants, agreement between self-report and electronic records for anthrax vaccination has been reported higher ($\kappa = 0.80$) than the current study found for smallpox vaccination.¹¹

Consistent with previous research, a higher percentage of participants with electronic documentation recalled receiving a vaccination (90%) than participants with no electronic record who reported not receiving a vaccination (82%).^{7,10,11,13} The finding of a lower agreement compared with anthrax vaccination in the Millennium Cohort is interesting. Self-reported vaccinations administered annually or in succession of doses, such as influenza and anthrax, tend to be more reliably recalled than vaccinations administered in a single dose or infrequently, like pneumococcal and smallpox.^{6,7,10} Primary vaccination against anthrax includes a six-dose series followed by an annual booster, whereas smallpox vaccination consists of one dose rarely followed by a booster.^{25,26} Even though it is administered in one dose, the smallpox vaccination is more distinct than other vaccinations, with vaccinees developing a skin reaction at the injection site that lasts up to three weeks and usually leaves a permanent scar.¹ Therefore, it seems likely that vaccinees would remember this vaccination. The largest source of disagreement (86%), however, is from those who stated they received a smallpox vaccination but did not have electronic documentation. Furthermore, the smallpox question on the survey asks if the vaccine was received in the past three years, whereas the anthrax question asks if the vaccine has ever been received. Since the smallpox vaccine was routinely administered to children in the United States until 1971 and to military recruits until 1990, it is possible that service members who received a smallpox vaccine during this time may have incorrectly reported receiving this vaccine on the questionnaire.¹ The agreement for those who were born before 1960 ($\kappa = 0.51$), who were likely vaccinated during this period, is low, suggesting they may have only received the smallpox vaccination as a child or as a military recruit. Furthermore, anthrax vaccination may be more easily recalled due to controversy surrounding the administration of the multi-dose vaccine.^{27,28}

Individuals who self-reported smallpox vaccination but did not have electronic confirmation were slightly less likely to have deployed in support of GWOT and more likely to be in the Navy/Coast Guard and work in functional support roles, when compared with participants whose electronic and self-report indicated vaccination. Differences among the service branches may be due to variations in procedures for reporting as well as administering vaccinations. For example, lower agreement ($\kappa = 0.41$) among Navy personnel could be explained by delays in shipboard vaccination reporting to the electronic system. Those with no deployment experience in support of GWOT had lower agreement ($\kappa = 0.35$) between electronic and self-reported vaccination status than the study population. The smallpox vaccination is often administered in conjunction with deployment, therefore those with recent deployment experience may recall their vaccination more easily because they were able to associate it with their deployment. The lower agreement among those not deployed in support of GWOT may also be associated with age, since those deploying tend to be younger. Moreover, the older group of nondeployers may be recalling childhood vaccinations. The lower kappa statistic among those not recently deployed, however, may also be attributed

to lower prevalence of vaccination among this group since the kappa statistic is dependent on the true prevalence of the examined variable and tends toward zero when the true prevalence is very high or low.²⁹

While there were some significant differences in SF-36V scores between the concordance groups, there was no apparent trend of reporting lower health measures. For social functioning and limitations caused by physical and mental problems, participants whose self-reported vaccination was not confirmed by electronic record had lower adjusted mean scores, indicating slightly worse health than those with concordant electronic and self-reported vaccination status. Those whose vaccination status agreed had significantly higher physical functioning and general health adjusted mean scores compared with the other concordance groups; those who reported no vaccination but had a vaccination recorded in the electronic records had a lower adjusted mean score for vitality compared with all other groups. In a previous study among Millennium Cohort participants, lower adjusted mean scores were found for all eight SF-36V scales among participants whose self-reported anthrax vaccination was not confirmed in the electronic records.¹¹ This indication that some Millennium Cohort participants may report more exposures as well as more health challenges was not as strongly supported among discordance of reporting in the current study. However, consistent with the previous vaccination study using Millennium Cohort data, there were no significant differences in the hospitalization experience between the smallpox vaccination groups for the one year prior to survey completion.¹¹

In the unfortunate event of a smallpox bioterrorist attack, vaccine doses will be limited in supply, and time will be of critical importance. Results of the current study suggest that 96% of those who report not being vaccinated are confirmed unvaccinated in the electronic database whereas 61% of those who self-report vaccination have electronic documentation of vaccination. While the smallpox vaccination scar may be used to identify those who are vaccinated, self-reported vaccination status could also be used as a screening tool to correctly identify those who have not been vaccinated. Though some individuals may be revaccinated, the biggest risk of misclassification and possible smallpox infection and transmission, would be among individuals who self-report being vaccinated who have not truly received the vaccination. Resources could then be better used to verify vaccination within medical records or immunization data for this smaller group who self-report receiving the smallpox vaccination.

This study has several limitations. The study population consists of a sample of Millennium Cohort participants and may not be representative of the military population in general. However, investigation of potential biases in the Millennium Cohort have found a well-representative military cohort who report reliable data and who are not influenced to participate by poor health prior to enrollment (Wells T, Naval Health Research Center, unpublished manuscript).^{11,17,30-35} Since a considerable percentage of military service members received a smallpox vaccine starting in early 2003, the dependence of the kappa statistic on the true prevalence of the examined variable should not substantially affect the findings of this study.²⁹ The Millennium Cohort questionnaire does not explain the administration process or typical skin reaction of the smallpox vaccination. Without this information participants may find it difficult to identify and report which vaccinations they have received. Finally, the amount of incomplete documentation for smallpox vaccination in the database remains unknown. While medical

records may have provided additional vaccination history, recent research indicates a strong level of agreement (sensitivity = 93.8%, specificity = 87.0%) between electronically maintained anthrax vaccination records and anthrax vaccination data abstracted from medical charts.³⁶

Despite these limitations, there are many strengths to these analyses. This study is the first large, population-based study of concordance between self-report and objective smallpox vaccination data. The unique opportunity to compare these data sources allows insight into the reliability of other self-reported measures on the questionnaire and is important for future longitudinal assessment when only self-reported data are available. The large sample size of this study allows for robust comparison of self-report and objective measures of smallpox vaccination. Further, this study was able to link both objective and subjective measures of morbidity to self-reported and electronic vaccination status.

Vaccination against biological agents is an important component of protection against bioterrorist attacks. During a time of crisis or bioterrorist attack, knowing the limitations and strengths of self-reported vaccination data is vital to the success and containment of emergency response efforts. Further, understanding the limitations and strengths of self-reported data in research allows for appropriate interpretation of results. Therefore, it is important to establish the reliability of self-reported data, such as smallpox vaccination, and to investigate differences in reporting based on health metrics. This analysis found substantial agreement between objectively maintained records and self-reported smallpox vaccination. Further, no substantial differences in health metrics were found among the small number of those whose recall of vaccination did not concur with their objective records. Overall results support that self-report of smallpox vaccination is a reliable measure of this important exposure.

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| 14. ABSTRACT (maximum 200 words) In December 2002, the US Government implemented policy to immunize health workers, first responders, and military personnel against smallpox in preparation for a possible bioterrorist attack. Self-reported vaccination data are commonly used in epidemiologic research and may be used to determine vaccination status in a public health emergency. To establish a measure of reliability, the agreement between self-reported smallpox vaccination and electronic vaccination records was examined using data from the Millennium Cohort Study. Descriptive measures and a kappa statistic were calculated for data from 54,066 Millennium Cohort Study participants. Multivariable modeling adjusting for potential confounders was used to investigate vaccination agreement status and health metrics, as measured by the Short Form 36-Item Health Survey for Veterans (SF-36V) and prior hospitalization data. Substantial agreement ($\kappa = 0.62$) was found between self-report and electronic recording of smallpox vaccination. Of all participants with an electronic record of smallpox vaccination, 90% self-reported being vaccinated; and of all participants with no electronic record of vaccination, 82% self-reported not receiving a vaccination. There was no significant difference in prior hospitalization experience between vaccinated and unvaccinated participants. While overall scores on the SF-36V suggested a healthy population, participants whose self-reported vaccination status did not match electronic records had slightly lower adjusted mean scores for some scales. These results indicate strong reliability in self-reported smallpox vaccination and also suggest that discordant reporting of smallpox vaccination is not associated with substantial differences in health among Millennium Cohort participants. | | | | | |
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